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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/025,635	02/18/1998	SHENG-ZHI PANG	19603/1552(I	9815

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EXAMINER

KUBELIK, ANNE R

ART UNIT PAPER NUMBER

1638

DATE MAILED: 12/26/2002

92

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	09/025,635	PANG ET AL.	
	Examiner	Art Unit	
	Anne R. Kubelik	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 October 2002.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-5, 9-12, 16-25, 27-36, 40-50, 53-62, 66-74 and 77-94 is/are pending in the application.
- 4a) Of the above claim(s) 21-22, 30, 44-45 and 82-92 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 9-12, 16-20, 23-25, 27-29, 31-36, 40-43, 46-50, 53-62, 66-74, 77-81 and 93-94 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on with the application is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All   b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

1. Claims 1-5, 9-12, 16-20, 24-25, 28-31, 33-36, 40-43, 46-50, 53-57, 59-62, 70-74, 77-81 and 93-94 have been amended and claims 6-8, 13-15, 26, 37-39, 51-52, 63-65 and 75-76 have been cancelled, as requested in Paper No. 120, filed 11 October, 2002. Claims 1-5, 9-12, 16-25, 27-36, 40-50, 53-62, 70-74 and 77-94 are pending. Claims 21-22, 30, 44-45 and 82-92 are withdrawn from consideration for being drawn to non-elected inventions. Claims 1-5, 9-12, 16-20, 23-25, 27-29, 31-36, 40-43, 46-50, 53-62, 66-74, 77-81 and 93-94 are examined.
2. This application contains claims 21-22, 30, 44-45 and 82-92 drawn to an invention nonelected with traverse in Paper No. 12. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144). See MPEP § 821.01.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Response to Amendment***

4. The objection to claim 19 under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim is WITHDRAWN in light of amendment of the claim.
5. The objection to claims 2-20, 23-26, 28-29, 31, 33-43, 46-57, 59-81 and 93-94 because of informalities is WITHDRAWN in light of amendment of the claims.
6. The rejection of claims 1-2, 6-9, 13-16, 18-20, 23-24, 26-29, 31-33, 37-40, 42-43, 46-47, 51-53, 55-59, 63-65, 68-71, 75-76, 80-81 and 93-94 under 35 U.S.C. 102(b) as being anticipated

by Seymour et al (1993, Plant Mol. Biol. 23:1-9) is WITHDRAWN in light of amendment of the claims to indicate that both the trait and silencer DNA molecules are heterologous to plants.

7. The rejection of claims 1-2, 6-8, 13-15, 17, 19-20, 23-24, 26-29, 31-33, 37-39, 41, 43, 46-47, 51-52, 54, 56-59, 63-65, 67, 69-71, 75-76, 78, 80-81 and 93-94 under 35 U.S.C. 102(b) as being anticipated by Van Blokland et al (1994, Plant J. 6:861-877) taken with the evidence of van der Krol et al (1990, Plant Mol. Biol. 14:457-466) is WITHDRAWN in light of amendment of the claims to indicate that both the trait and silencer DNA molecules are heterologous to plants.

#### ***Response to Arguments***

8. The rejection of claims 1-5, 9-12, 16-20, 23-25, 27-29, 31-36, 40-43, 46-50, 53-62, 70-74, 77-81 and 93-94 under 35 U.S.C. 112, first paragraph, set forth on 4-5 of the Office action mailed 11 April 2002, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is WITHDRAWN in light of Applicant pointing to support for the phrases.

#### ***Claim Rejections - 35 USC § 112***

9. Claims 1-5, 9-12, 16-20, 23-25, 27-29, 31-36, 40-43, 46-50, 53-62, 66-74, 77-81 and 93-94 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The rejection is repeated for the reasons of record as set forth in the Office action

mailed 11 April 2002, as applied to claims 1-20, 23-29, 31-43, 46-81 and 93-94. Applicant's arguments filed 11 October, 2002, have been fully considered but they are not persuasive.

Applicant urges that the specification teaches that a silencer DNA can be used to couple fragments of different coat protein encoding genes from different strains of papaya ringspot virus to produce ringspot resistant papaya, and that the specification teaches that coat proteins genes from different papaya ringspot virus strains can be used. Applicant also urges that the specification teaches that coat protein genes from different viruses can be used in combination. Applicant urges that the subject matter of the instant application is not new naturally-existing DNA molecules but a new use for known sequences (response pg 11-12).

This is not found persuasive because "trait DNA molecule" and "silencer DNA molecule" are not described in the specification such that one would know the structural features that distinguish trait and silencer DNA molecules from other nucleic acids or from each other. The claims are not limited to coat protein genes from different viruses. Claim 1, as written, encompasses any "trait", and thus encompasses any DNA. Given that "trait DNA molecule" reads on everything from dinucleotides to entire chromosomes, more written description must be provided.

10. Claims 1-5, 9-12, 16-20, 23-25, 27-29, 31-36, 40-43, 46-50, 53-62, 66-74, 77-81 and 93-94 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for DNA constructs comprising a trait DNA molecule from the tomato spotted wilt virus and silencer DNA molecules that are the green fluorescent protein and the turnip mosaic potyvirus coat protein genes, a method of using them to impart the trait of resistance to turnip mosaic potyvirus and tomato spotted wilt virus to a plant, and plants so transformed, does not reasonably provide enablement for DNA constructs comprising any trait DNA and any silencer

DNA and methods of using them to impart any trait. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The rejection is repeated for the reasons of record as set forth in the Office action mailed 11 April 2002, as applied to claims 1-20, 23-29, 31-43, 46-81 and 93-94. Applicant's arguments filed 11 October, 2002, have been fully considered but they are not persuasive.

Applicant urges that Examples 1-5 of the specification teach how to prepare constructs of different lengths and that one of skill in that art would be able to do the same (response pg 13-14).

This is not found persuasive because in the interview conducted on 6 November 2002, with the inventor and the Applicant's representative, the inventor, Dennis Gonsalves, stated that the silencer has a minimum length requirement of 400 nucleotides and the trait has a minimum length requirement of 110 nucleotides. Additionally, Jan et al, cited in the prior Office action, teach that the minimum length of the N gene trait DNA in such a gene-silencing construct was 110 nucleotides (pg 239, paragraph spanning the columns). The instant specification teaches that "any viral sequence longer than 110 bp can be used" (pg 45, lines 21-22). Thus, these limitations should be in the claims.

11. Claims 1-5, 9-12, 16-20, 23-25, 27-29, 31-36, 40-43, 46-50, 53-62, 70-74, 77-81 and 93-94 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Dependent claims are included in all rejections. The rejection is repeated in part for the reasons of record as set forth in the Office action mailed 11 April 2002, as applied to claims

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1-20, 23-29, 31-43, 46-81 and 93-94. Applicant's arguments filed 11 October, 2002, have been fully considered but they are not persuasive.

The claims are indefinite in their use of the terms "trait DNA molecule" and "silencer DNA molecule". Applicant urges that a trait DNA is one that has an insufficient length to independently impart a trait and the silencer DNA is one that is effective to achieve post-transcriptional silencing, and whether a silencer DNA encodes a protein is not relevant (response pg 14). This is not found persuasive because it is unclear what DNAs are encompassed by each. As the silencer DNA can encode a protein (*e.g.*, pg 19, lines 4-16), it would also appear to be a "trait DNA". Thus in claims like 2, can both the "trait DNA" and the "silencer" of claim 1 be the "plurality of trait DNAs" in the construct?

Claim 1 is indefinite in its recitation of "effective to achieve post-transcriptional silencing" and claim 20 is indefinite in its recitation of "effects post-transcriptional silencing". Applicant urges that "post-transcriptional silencing" is explained on pg 6, line 5, to pg 10, line 13, and pg 18, line 32, to pg 19, line 3 of the specification (response pg 14). This is not found persuasive because it is unclear what is being post-transcriptionally silenced.

The following rejection is new, as a result of amendment to the claims:

Claim 57 and 81 lack antecedent basis for the limitation "the transgenic plant" in line 2.

### ***Claim Rejections - 35 USC § 102***

12. Claims 1-5, 9-12, 16-17, 19-20, 23-25, 27-29, 31-36, 40-41, 43, 46-50, 53-54 and 56-57 remain rejected under 35 U.S.C. 102(b) as being anticipated by Lawson et al (1990 Bio/Technol. 8:127-134). The rejection is repeated for the reasons of record as set forth in the Office action mailed 11 April 2002, as applied to claims 1-5, 8-12, 15-17, 19-20, 23-25, 27-29, 31-36, 39-41,

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43, 46-50, 53-54, 56-57 and 93-94. Applicant's arguments filed 11 October, 2002, have been fully considered but they are not persuasive.

Applicant urges that the coat protein genes used by Lawson are sufficient to impart resistance and that the two genes have their own separate promoters (response pg 15).

This is not found persuasive because in the constructs taught by Lawson et al, at least two nucleotides are the trait DNA, which would be insufficient to impart the trait and the rest of the coat protein gene would be the silencer DNA. The trait DNA and the silencer DNA would be heterologous to one another because a dinucleotide could be derived from any source. The construct is expressed from a single a CaMV 35 S promoter and a RuBP carboxylase E9 terminator. The constructs have a plurality of different trait DNA molecules, each with their own promoter, and each provided viral disease resistance.

Lawson et al also teach a method of imparting the trait(s) to potato plants by transformation with an expression vector comprising the construct, plants so transformed, and methods of propagating progeny by regeneration of tubers (pg 129, left column, paragraph 3, and pg 130, right column, paragraph 3-4).

13. Claims 1-4, 9-11, 16-17, 19-20, 23-25, 27-29, 31-35, 40-41, 43, 46-49, 53-61, 66-67, 69-74, 77-78, 80-81 and 93-94 remain rejected under 35 U.S.C. 102(a) as being anticipated by Tricoli et al (WO 96/21031). The rejection is repeated for the reasons of record as set forth in the Office action mailed 11 April 2002, as applied to claims 1-5, 8-12, 15-17, 19-20, 23-25, 27-29, 31-36, 39-41, 43, 46-50, 53-54, 56-62, 65-67, 69-74, 77-78, 80-81 and 93-94. Applicant's arguments filed 11 October, 2002, have been fully considered but they are not persuasive.

Applicant urges that the DNA sequences used by Tricoli each have their own promoter (response pg 15-16).



This is not found persuasive because Tricoli et al teach a vector comprising a DNA construct, pPRCPW, that comprises the "trait DNA" of the amino terminal portion of the cucumber mosaic virus (CMV) coat protein ORF and a silencer DNA, the watermelon mosaic virus-2 (WMV-2) coat protein ORF (pg 22, lines 15-28, and Figure 3). The trait DNA and the silencer DNA are heterologous to each other and to plants, and are transcribed from a single promoter, the CaMV 35S promoter, and a single termination signal is present in the construct. Tricoli also teach squash plants and seed transformed with the construct (pg 26, line 10, to pg 27, line 8, and pg 30, lines 15-26).

***Claim Rejections - 35 USC § 103***

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. Claims 1-5, 9-12, 16-20, 23-25, 27-29, 31-36, 40-43, 46-50, 53-62, 66-74, 77-81 and 93-94 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tricoli et al (WO 96/21031).

The claims are drawn to constructs comprising a trait DNA molecule and a silencer DNA molecule, wherein the two are heterologous to each other and heterologous to plants and are transcribed from a single promoter, and also comprising a trait DNA from papaya ringspot virus, vectors, cells, plants and seeds transformed with the constructs and methods of using them to impart traits to plants.

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Tricoli et al teach a DNA construct, pPRCPW, that comprises the “trait DNA” of the amino terminal portion of the cucumber mosaic virus (CMV) coat protein ORF and a silencer DNA, the watermelon mosaic virus-2 (WMV-2) coat protein ORF (pg 22, lines 15-28). Both genes are longer than 110 bp. The trait gene is insufficient to impart the trait but the silencer and trait DNAs together can impart the trait. Additionally, the silencer DNA can be considered a trait DNA, so the construct would comprise a plurality of different trait DNAs, at least one of which is insufficient to impart the trait and at least one is long enough to impart the trait. A CaMV 35S promoter drives transcription and the construct comprises a termination signal.

Tricoli et al do not disclose constructs comparing a trait DNA molecule and a silencer DNA molecule, wherein the two are heterologous to each other and heterologous to plants and are transcribed from a single promoter, and also comprising a trait DNA from papaya ringspot virus.

Tricoli et al also teach DNA constructs comprising multiple trait DNA molecules on the DNA construct, with various combinations of the CMV coat protein ORF, the zucchini yellow mosaic virus coat protein ORF, and the WMV-2 coat protein ORF, and a papaya ringspot virus ORF (pg 25-26). The ORFs would encode RNAs that are translatable.

Tricoli et al also teach squash, cantaloupe, cucumber and watermelon plants transformed with expression vectors comprising these constructs, and R<sub>1</sub> and R<sub>2</sub> seeds and plants produced from the transgenic plants (pg 26-39).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to modify the construct taught by Tricoli et al, to add an additional trait DNA, including one that comprises a cDNA from papaya ringspot virus or to include the papaya ringspot virus coat protein gene in the fusion gene of the construct. One of ordinary skill in the art would have

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been motivated to do so because of the success Tricoli had in obtaining plants with resistance to multiple viruses (pg 26-39), and because the exact combination of viral resistance sequences used in a particular construct is an obvious design choice. Tricoli et al also suggest using DNAs that encode RNAs that are non-translatable (pg 19, lines 12-17).

### *Conclusion*

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (703) 308-5059. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the patent analyst, Kimberly Davis, at (703) 305-3015.

Anne R. Kubelik, Ph.D.  
December 23, 2002



**AMY J. NELSON, PH.D.  
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